

A HealthTech Report

Evaluation of a Disposable Needle-Removal Device in Uganda

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Executive Summary

PATH conducted an evaluation of a disposable needle-removal device (the Hub Cutter, manufactured by BD™) over a three-month period from November 2004 through February 2005 in 12 health facilities in Kampala, Uganda, where Depo-Provera (an injectable contraceptive hereafter referred to as Depo) and other injections are delivered. The primary objective of this study was to evaluate the overall fit of the device in family planning settings where injectable contraceptives, particularly Depo, are delivered. A secondary objective was to evaluate the effect needle-removal devices have on volumes of sharps waste. The study was funded by USAID Office of Population under the USAID-supported HealthTech project as part of an effort to collect information on injection safety in the context of delivery of injectable contraceptives.

Over the three-month period, 158 Hub Cutters and 368 safety boxes were distributed. Data were collected on 51,734 injections. The Hub Cutter was found to fit well into many of the systems in the Kampala clinics. The device was well accepted by study participants who reported that it was extremely dependable and easy to use. Two devices out of 158 failed to work during the study. Health workers and waste handlers described an increase in the overall cleanliness of their health facilities with the introduction of the Hub Cutter.

The Hub Cutter effectively reduced volumes of clinical waste by approximately 35 percent and allowed consideration of the use of infectious waste bags for disabled syringe barrels.

The main concerns associated with the Hub Cutter were final disposal and incompatibility with some sizes of needles. The study highlighted the lack of priority, budgets, and systems for collection, transport, and final disposal of all health care waste.

Although there were clear advantages to use of the Hub Cutter, it is not likely to be of sufficient benefit if introduced as part of only one vertical program. The Hub Cutter's unique features may be of greater benefit as part of outreach efforts or in remote, rural settings.

Introduction

Background

Each year, more than 16 billion injections are administered worldwide.¹ In some regions, 17 percent to 75 percent are estimated to be with reused, unsterilized injection equipment.² Unsafe reuse of needles and syringes is estimated to cause 20 million hepatitis B infections, 2 million hepatitis C infections, and 250,000 HIV infections annually.³ The main tools to prevent reuse of unsterile syringes and needles are autodisable (AD) syringes and safety needles and syringes. Appropriate disposal of sharps and syringes also play a role in safe injection and prevention of reuse. World Health Organization (WHO) guidelines recommend disposal of used syringes and needles in cardboard safety boxes that are then usually burned or incinerated. In developing countries, where reuse is most prevalent, safe sharps disposal policies and practices are often inadequate. Assessments in six African countries, China, and India showed that health workers often mix sharps waste into other waste streams, dispose of waste haphazardly in and around their clinics, and do not have regulated systems for safe disposal of sharps waste for all injections.^{4,5,6}

In August 2002, DELIVER project staff conducted a pilot assessment in Uganda on the introduction of AD syringes and safety boxes for use with Depo-Provera (Depo) injectable contraceptive.⁷ The qualitative assessment in 30 family planning facilities concluded that sharps disposal was the most serious issue to be addressed with regard to Depo use. In spite of sincere efforts by many providers, waste disposal practices were highly variable and inadequate. Fewer than half of the providers at the 19 sites that were visited practiced safe disposal techniques. Sharps disposal practices observed were needle recapping, manual separation of needles and syringes, emptying contents of safety boxes into pit latrines or other deep pits, open burning, leaving needles and syringes in areas open to access by the public, transporting needles and syringes in inadequately sealed containers, and emptying contents from one container into another. Ministry of Health (MOH) respondents mentioned lack of paraffin (kerosene) for operating the incinerator as a major problem requiring them either to stockpile safety boxes or to send sharps to another site for burning. Safety boxes provided by the Uganda National Expanded Program on Immunization (UNEPI) improved waste disposal practices, but required kerosene for burning, and took up substantial warehouse space.

As part of its concerted efforts to reduce the prevalence of HIV/AIDS, the Government of Uganda has committed to reduce disease transmission from unsafe injection practices. The MOH created the Uganda National Injection Safety Task Force (UNISTAF) to improve coordination and to develop a National Injection Safety Policy. In 2003, UNISTAF hired a consultant from BASICS/Washington, DC to conduct an assessment of injection practices. The study concluded there was an urgent need for a national policy to reduce reuse of needles and syringes and to improve sharps waste collection and management. The study found that in 19 percent of the 80 facilities observed, there were no puncture-proof sharps containers where injections were given; 31 percent of facilities used open burning of waste; 35 percent of facilities burned waste in a shallow pit or enclosure, and in 38 percent of facilities, sharps and other waste were observed on the grounds.⁸

The Ugandan MOH has since drafted a national policy on injection safety and health care waste management. In 2004, Uganda was selected as one of 12 countries to participate in the Centers for Disease Control and Prevention (CDC) and USAID-funded Making Medical Injections Safer project (MMIS). MMIS is operating in four Ugandan districts, Mpigi, Pallisa, Mbarara, and Nebbi, and addresses procurement of safe injection equipment and strengthening of waste management programs. As part of the government's effort to improve the safety of injections in Uganda, AD syringes are increasingly being used both in UNEPI and family planning settings.

Strategy

This study was undertaken to examine needle removal and its role in disposal of sharps waste disposal. A needle-removal device allows the injection provider to immediately remove the needle from a syringe and contain it in a small, puncture-resistant container. The process results in two waste streams—the isolated needles and the “defanged” disabled syringes. Isolated needles in disposable needle removers may be buried or disposed of in the same way as a safety box. The defanged syringes are no longer sharps waste and can be collected in various ways, such as in a safety box or with other infectious waste in plastic bags, and can be disposed of according to local practice.

In several recent field evaluations, manual needle removers have been found by health workers to be a durable and well-accepted means of managing sharps waste in immunization settings.

However, data are needed on how a needle remover fits in settings where family planning services, specifically Depo injections, are delivered including the durability and acceptability of such a device in these settings. Data are also needed on the effect that needle-removal devices have on volumes of sharps waste.

Methods

Goals and Objectives

The primary objective of this project was to evaluate the overall fit of a disposable needle-removal device (the Hub Cutter) in family planning settings where injectable contraceptives, particularly Depo, are delivered. USAID Office of Population, which funded the study under the HealthTech project, is interested in the issue of injection safety in the context of delivery of injectable contraceptives. A secondary objective was to evaluate the effect needle-removal devices have on volumes of sharps waste. To assess the fit with systems where family planning services, including Depo injections, are delivered, the project collected quantitative and qualitative data on device function, ease of use, durability, storage, disposal, systems of distribution, and training. Focus group discussions and in-depth interviews were conducted with facility managers, decision-makers, injection providers, and waste handlers to assess acceptability and fit with the system. Another secondary objective was to compare volume of syringe and needle waste in sites with and without needle removers.

Study Materials

The Hub Cutter, developed by BD, is a lightweight, plastic, disposable needle-removal device. It has a lockable cap covering an opening at the top into which a used syringe with needle is firmly inserted (see Figure 1). When the two sides of the Hub Cutter device are squeezed together, a blade in the opening cuts the needle from the syringe's hub. The needle is collected in the plastic Hub Cutter device, which is disposed of when full—the device holds 400 to 600 needles. The Hub Cutter is not designed to cut the metal needle cannula—doing so will damage the blade. The study protocol recommended that Hub Cutters be disposed of according to Ugandan policy guidelines, either by incineration or by deep burial in sharps pits, where appropriate. It is made of non-PVC plastics that can be incinerated without causing harmful emissions. The Hub Cutter was previously evaluated in China, Eritrea, and Madagascar.⁹ PATH bench testing found the device to work efficiently with eight different syringes.



Figure 1. BD Hub Cutter

Study Design

The study was conducted over a three-month period from November 2004 through February 2005 in 12 health facilities in Kampala, Uganda, where Depo and other injections are delivered. Facilities were selected to represent government, non-governmental organizations, and private-sector clinics. Facilities were also selected on the basis of both higher and lower injection volumes, ease of monitoring, and inclusion of outreach activities. The study was conducted primarily in immunization clinics, family planning clinics, out-patient departments, and outreach services; but in several facilities, maternities and laboratories were also included. The study was carried out by PATH staff in Seattle and Uganda, and by a consultant hired as the study monitor from the Uganda Ministry of Health, District Director of Health Services, Kampala City Council. The PATH ethical review board and the Ugandan MOH reviewed and approved the study protocol.

The 12 sites were divided into the following groups:

- Ten intervention facilities where the Hub Cutter device and 5-liter Polynor safety box were both used.
- Two control facilities where the 5-liter Polynor safety box was used.

Table1. Device Distribution

Facility	Safety Boxes Distributed During Study	Hub Cutters Distributed During Study
1	19	N/A
2	56	N/A
3	38	16
4	38	21
5	15	16
6	22	9
7	35	16
8	41	18
9	17	7
10	50	32
11	20	11
12	17	12
Total	368	158

Log books with data collection forms were provided to managers and injection providers at each facility.



Figure 2. Manager Training

The study consisted of the following elements:

- Training on study components, including forms completion, needle remover device and safety box use (intervention facilities), and safety box use only (control facilities).
- Safe injection training (intervention and control facilities).
- Provision of needle-removal devices (intervention facilities).
- Provision of 5-liter safety boxes (intervention and control facilities).
- Routine supervision by study monitor (intervention and control facilities).
- Photos and/or videotaping of device and safety boxes in use (intervention and control facilities).
- Focus group discussions (FGDs) and in-depth interviews (intervention and control facilities).

Participants

There were 73 participants in the evaluation, comprising 12 facility managers, one from each facility, and 61 health workers. Among the health workers who participated were injection providers and waste handlers. The injection providers administered Depo and other injections, and waste handlers were responsible for the waste handling, transport, and disposal.

Training

The 12 facility managers attended a one-day training in Kampala in early November 2004. In addition, a total of 61 injection providers and waste handlers representing all 12 facilities attended two separate one-day trainings also held in November 2004. The trainings were

conducted by PATH staff from Uganda and Seattle, and oversight was provided by the study monitor from Kampala City Council. Training included an overview of injection safety and of the study, a discussion of current safe injection practices, instructions and practice on Hub Cutter and safety box use, roles and responsibilities of each participant, and how to complete data forms. A summary of the topics covered in the training are included in Appendix A. Instructions for use were developed for both the Hub Cutter and safety box and given to each intervention facility to post at injection locations (Appendices B and C). Training was conducted in English with translation into Luganda for waste handlers.

Monitoring and Data Collection

Monitoring

A senior nurse health visitor, Sister Helen Oluka from Kampala City Council, Office of the District Director of Health Services, was hired as the study monitor. She provided primary study oversight and ensured good linkages and communication with the MOH. The study monitor visited each site at least once every two weeks. During these facility visits the monitor observed, assessed, and documented proper use of the Hub Cutter and safety box including their location in relationship to the injection provider, correct completion of data collection forms, and whether there were sufficient supplies of working needle removers and safety boxes. During site visits, the study monitor completed a monitor's log and wrote a brief report summarizing her findings and actions. She also reviewed injection provider and manager logs for accuracy and completion.

Data Collection

Data were collected by the following methods:

Quantitative

In addition to the biweekly monitor's site visit logs, facility managers completed weekly data-collection logs, and injection providers completed daily data logs (sample forms are included as Appendices D, E, F, and G).

The following data were collected:

Volumes

- Number of filled needle removers
- Number of filled safety boxes
- Number of syringes used

Device failures

- Number of needle-remover device failures
- Number of needle-remover devices removed from study due to failure
- Number of syringes used at the point of failure

Qualitative

The FGDs and in-depth interviews were conducted by qualitative investigators from the Rakai Health Sciences Program, Uganda, in collaboration with PATH and the study monitor.

In February 2005, four FGDs and three in-depth interviews were carried out with men and women who participated in the intervention and control arms of the study. The FGDs and interviews were held in Kampala with 8 waste handlers from intervention sites, 7 injection providers from control sites, 12 injection providers from intervention sites, and 8 managers of intervention sites. In-depth interviews were carried out with two waste handlers from control sites and one injection provider from a control site.

Four separate research instruments were developed to guide individual discussions with each of the four categories of participants (waste handlers from intervention sites, injection providers from control sites, injection providers from intervention sites, and managers of intervention sites). The FGD guides were adapted as necessary for the in-depth interviews (see Appendix H for a sample FGD guide).

The FGDs and the two interviews with waste handlers were conducted in Luganda. The third interview and all other focus groups were conducted in English. The audiotapes of the FGDs and interviews with waste handlers were translated and transcribed into English text. The other interview and focus group discussions were transcribed into English. All written transcripts were then entered into a word processing program. Electronic copies were provided to the investigators for analysis. The data were exhaustively reviewed by the three qualitative researchers for main themes, transcripts were then individually reviewed, and manual coding and analysis was completed. Matrices of interconnections of the areas of interest were constructed to condense and organize the data and to simplify cross-informant/cross-group analysis. Finally, themes were generated to represent the ideas or experiences of a large proportion of participants and informants.

In addition, during the study, participants were observed and photographed and/or videotaped while using the Hub Cutter and safety boxes.

Results

Fit with System

Locations of Use

FGD and monitor's reports indicate that Hub Cutters and safety boxes were kept within arm's length of the injection providers so that they could dispose of sharps and syringes immediately after administering each injection without the need to physically move. Some kept the Hub Cutter on the top shelf of the trolley that held all medical/clinical equipment and supplies, while others kept it on the top of a table. Participants reported that the safety box was kept on the lower shelf of the trolley or on the floor. Hub Cutters were not moved from ward to ward. The study did not introduce the Hub Cutters in labor wards or dental clinics where volumes of blood were likely to be greater. Study participants requested that the Hub Cutter be adapted for use in such settings. Hub Cutters were taken on outreach visits by health providers who administered injections away from their base stations. Hub Cutters were easy to transport on outreach visits; no one reported that they lost track of them. Some

managers mentioned that health workers left the safety boxes at the outreach sites because they had too much to carry. Initially Hub Cutters were taken for outreach visits but over time the frequency of outreach visits and/or volume of patients at outreach settings was deemed too low to merit the need for taking the Hub Cutter to each site. Some participants wanted Hub Cutters and safety boxes to be in place at each of the outreach sites to eliminate carrying these devices back and forth. Others, however, felt strongly that the devices should not be left at outreach settings because when the health workers are not present, the outreach sites are managed by nonmedical people who might misuse, damage or remove the Hub Cutters and/or safety boxes.

System of Distribution

Managers were asked “If a Hub Cutter was provided for every one hundred AD syringes and doses of Depo you received, how would this affect your clinic?” The study managers came from health centers with a diverse range of services, and all felt that injection safety should not be promoted only in family planning clinics. Study data showed that Depo injections represented approximately seven percent of the total number of injections delivered in the twelve facilities. Hub Cutters were therefore used primarily for disposal of needles and syringes used for immunization, outpatient, and outreach injections and not for those delivered in family planning clinics. Study participants recommended that Hub Cutters be bundled with syringes and medications for all injections, not just family planning.

Final Disposal

All FGD participants reported having a proper location for storage of the full Hub Cutters and safety boxes prior to disposal. Some waste handlers from intervention sites explained that they disposed of the full Hub Cutters themselves. Some of the facilities burned the safety boxes and Hub Cutters on site. Hub Cutters were burned with paraffin, often in an unused, enclosed pit latrine. It was explained, however, that some needles within the Hub Cutters do not burn completely and require a final step of disposal. After the safety boxes and Hub Cutters had been burned to ash, the waste handlers swept the remains (including unburned needles) together, dug a hole in the ground and buried everything. It was felt that this practice had the potential for risk of needlestick injury. The study monitor and PATH staff discouraged this method of disposal and assisted with transport to incinerators.

To facilitate safe disposal of the Hub Cutters, the study monitor arranged their transport to the nearest incinerator and paid for incineration costs. The cost to incinerate was US\$ 2,500 per kg of waste. The incinerator operator at Mulago Hospital reported that destroying the Hub Cutters posed no problem and that in fact the two large incinerators at Mulago do not operate often enough because of lack of full loads of waste. Therefore, capacity was not a problem, and he welcomed waste from other facilities.



Figure 3. Hub Cutter Device in Use

Although none of the waste handlers were burying full Hub Cutters in deep pits without burning, they were aware that this was a possible mode of disposal. None supported this method of disposal. Views surfaced about the extended period of time it would take for the plastic Hub Cutter to biodegrade.

Sincerely with burying - the earth can't bear the waste very easily, it take a long time to rot. You never know when someone will get to that place for digging and expose them out. Whereas with burning (Hub Cutters) they are burnt completely and will turn to ash. Even if the remains are there, they will not be so dangerous, they will have been worn so I recommend that we burn and bury after burning.

—Participant from FGD with waste handlers from intervention site.

Participants felt the Hub Cutter had a positive impact on waste disposal at their sites. However, some waste handlers admitted it was difficult to get rid of the Hub Cutter because it was such an attractive device. In contrast, none of the waste handlers felt attached to safety boxes.

I really miss this nice looking cutter when it's thrown away. [the group laughs]. I asked the person who trained us if it was possible to empty it for re-use. They refused and said that it's disposed. You know it's just taken away. This hub cutter could be re-used for a year.

—Participant from FGD with waste handlers from intervention site.

Function and Durability

Ease of Use

All FGD participants gave an overall positive evaluation of the Hub Cutter in terms of reliability, maintenance, and ease of use. It was reported that the device was extremely dependable and easy to use. Additionally, participants felt that in most cases the Hub Cutter effortlessly cut needles from their syringes. Its use was simply described as “very easy.” Participants also described maintenance (cleaning and storage) of the Hub Cutter as being “very easy.”

...we would get cotton with Jik [bleach] and clean the inner part but without dropping Jik on that blade. We would then dry it and cover it.

—Participant from FGD with injection providers from intervention site.

The main disadvantages associated with the Hub Cutter were that it could not be used with all sizes of needles, could not be used in all injection settings, the caps did not seem to be strong, some Hub Cutters were faulty, and some devices did not work well for a very long time. Participants reported that the Hub Cutter worked well with 2 ml syringes but the 5 ml syringes, and anything larger, were hard to cut. In addition, very small needles/syringes, as used for BCG vaccinations, were difficult to use in the Hub Cutter because the entire needle and syringe would fall through the hole and into the device. Following the monitor's reports of this concern, the study team recommended that BCG syringes be put into safety boxes and not cut in the Hub Cutter.

Four of the 1,309 daily log responses were that the Hub Cutter did not work versus 1, 274 responses of it working very well (see Table 2). Some of the Hub Cutters distributed during the study only worked well when they were brand new or stopped working before they

became completely full. Several participants mentioned that after using the Hub Cutter for approximately two weeks, the blade of the device would become dull or blunt, and it would be very difficult to cut the needles, especially the 5 ml syringe. To compensate for the dull blade, some of the injection providers managed to succeed in cutting needles by using great force or squeezing the Hub Cutter more than one time.

Table 2. Reported Performance of the Safety Box and Hub Cutter

Facility	Device in Use	Very Well	Satisfactorily	Poorly	Did not work
1	Safety Box	37			
2	Safety Box	299	3		
Total		336	3		
3	Hub Cutter & Safety Box	192	5	2	
4	Hub Cutter & Safety Box	142	5	2	
5	Hub Cutter & Safety Box	108	3		
6	Hub Cutter & Safety Box	80		2	1
7	Hub Cutter & Safety Box	41			1
8	Hub Cutter & Safety Box	194		4	
10	Hub Cutter & Safety Box	156	2	5	
11	Hub Cutter & Safety Box	96	1		2
12	Hub Cutter & Safety Box	181			
Total		1190	16	15	4

Learning

All focus group participants who attended the study training in November 2004 said that it was extremely easy to learn how to use the Hub Cutter and that the training was sufficient. Those who did not attend the training also felt it was easy to learn how to use the device by learning from those who had attended the training, reading the instructions attached to the side of the Hub Cutter, or reading the materials posted on the wall. Those who were instructing others “on the job” concurred, saying that they felt it was simple to convey the instructions for use of the Hub Cutter.

Device Failures

There were 15 incidents of device malfunctions reported out of the 47,758 injections given during the three-month evaluation. Of the 15 devices that malfunctioned, two devices were removed from use; the others were returned to use. Descriptions of the malfunctions included six reports of “took more than three attempts to remove needle,” two reports of “a lot of force was required to cut the syringe,” four reports of a “partially cut syringe,” and three reports that the Hub Cutter “did not cut the syringe.”

Cleaning

Injection providers agreed that maintenance of the Hub Cutter was easy. Some facilities had a practice of cleaning the device after each use, others cleaned it periodically throughout the day, while others cleaned it at the beginning or end of each day or as was needed. None of the participants suggested that maintenance of the Hub Cutter was overly cumbersome and instead they compared it to maintaining a safety box.

Perceptions of Safety

There was a unanimous view among FGD participants that the use of the Hub Cutter increased safety in and around health facilities. Specifically, it was reported that the device decreased the risks of needlesticks and contamination to health workers, clients, waste handlers and the community at large. The health workers reported that none of them nor any of their injection-providing coworkers had experienced a needlestick since the introduction of the Hub Cutter. This seemed to significantly ease fear of needlestick that was reported to exist prior to the introduction of the Hub Cutter and safety box combination. The managers disclosed that previously a great challenge of their work was instructing others to dispose of clinical waste. Prior to the study, in addition to safety boxes, some facilities contained sharps waste in buckets, large plastic bags, jerry cans, metal drums, makeshift boxes or other types of waste containers. Participants reported that in some sites, all clinical waste was being placed in large plastic bags, which needles and other sharps punctured. Health workers and waste handlers were reluctant to carry the large plastic bags of medical waste or to empty out the bucket of sharps. These fears were alleviated when sharps waste began to be stored in Hub Cutters and safety boxes. Health workers and waste handlers now feel safe and confident about dealing with sharps waste.

“Previously, because of that polythene bag, you could find needles passing through, including sharps, other sharps. So they were even fearing to carry it. So when this method was introduced in the clinic, there is no need of waiting, “So and so should burn,” no, they just do it immediately every morning.”

—Participant from FGD with managers of intervention site.

Waste handlers noted that previously the injection providers would be careless about disposing of their waste and waste handlers would often find needles and syringes scattered on the floor. Gathering this waste from the floor was risky for the waste handlers. Introduction of the Hub Cutters has therefore increased their safety.

“This study has greatly helped us people who have been handling waste for burning. Currently we note that the Hub Cutter can take about three days before it’s filled up with needles and the safety box also takes about three days to get full. Previously we used to collect sharps in a container from where we could collect them for disposal. Sometimes they may be scattered around. The injection providers sometimes could continue disposing these sharps in containers even when they were full. But now with the use of a Hub Cutter, the injection providers are concerned, they pay more attention and enjoy the process of cutting off the needles. When the Hub Cutter gets filled up, they quickly ask for another one.”

—Participant from FGD with waste handlers from the intervention site.

Additionally, it was agreed that the Hub Cutters increased the safety of the community. Several participants mentioned that in the past, sharps waste was disposed of in a way that allowed people in the community access to the used needles and syringes, especially children and farmers.

“...you know we are surrounded by many people who keep poultry and have interest in syringes. Before the waste is burnt they take the syringes for their use on poultry farms. But with the introduction of the hub cutter and safety boxes, the used syringes are not useful to them and they no longer take them.”

—Participant from FGD with waste handlers from intervention sites.

In addition to believing that use of the Hub Cutter decreased risks of needlestick injury, it was unanimously felt that the presence and use of the device built confidence among clientele. Patients who came to injection sites where the Hub Cutter was being used saw the device destroying the needle that had provided them with an injection. This succeeded in dispelling potential fears about needle reuse at the facility.

“The Hub Cutter has done us a lot of good because we know that we are really safe....it has also created the confidence of people in the community who knew that these (needles) were disposed of.” —Participant from FGD with managers from intervention sites.

In a private-sector facility there was a reported increase in clientele; according to a manager, clients commented that they were coming because of the “new technology.”

“We are now sure these needles are destroyed. No way they could be reused.”
—Participant from FGD with managers at intervention sites.

Use of Safety Box Alone

Safety boxes were being used without Hub Cutters in two facilities in family planning, outpatient departments, immunization centers, pediatric wards, maternity wards, and

outreach sites. Participants' prior experience with the safety boxes equipped some of those in the control sites with the confidence to properly do their work. For those who did not have this past experience, the training on injection safety and use of the safety box conducted in November 2004 was reported to have significantly strengthened control participants' skills to use the safety box in a safe and effective manner.

The training effectively emphasized the need to separate clinical waste and to use the safety boxes only for needles, syringes, and other sharps waste. Many participants explained that prior to the training it was common for health workers in their sites to throw other types of waste in the safety boxes or otherwise designated sharps containers. Participants also reported that as a result of the training they no longer recapped needles or tried to separate needles and syringes before placing them in the safety box. The training also reinforced the importance of always having a safety box on hand and available, as opposed to sharing the device between different wards and/or neglecting to carry it to outreach settings.

When asked how the introduction of the safety box made life as an injection provider different, one participant explained:

"We used to injure ourselves, because we could remove the needle, separate them and put them in the container. There was a lot of contamination." —Participant from FGD with injection providers from control sites.

All injection providers from the control sites said that the safety boxes were always kept close to the health workers who provide injections at their facility. All participants seemed to have a clear understanding of how important it was for the safety box to be located close by so that health workers could dispose of sharps and syringes immediately after administering each injection without the need to get up (physically).

Safety boxes were not taken from ward to ward, but they were taken on outreach. As reported by health workers from control sites, injection providers often found transportation of the safety box to be cumbersome and subject to being left behind. Carrying the safety box was primarily a problem for those health workers who had to rely on public transportation. Regardless of the type of transportation, participants from both control and intervention sites reported forgetting the safety box at the outreach sites.

All health workers reported that the safety boxes were reliable—none mentioned problems such as difficulty with assembling the safety boxes, boxes falling apart or breaking, or boxes filling too quickly. Injection providers reported no experiences of safety boxes leaking or sharps waste spilling over or puncturing the box. However, during the focus group discussion with waste handlers, several participants disclosed having worries about or actual experience with leaking/wet safety boxes. A general concern among waste handlers was that many syringes are disposed of with retained fluid which is subject to leakage. Nonetheless, no serious adverse experiences (of leakage or breakage) were reported during data collection.

Unlike with the Hub Cutter, those using the safety box explained that all sizes of sharps, syringes, and needles fit in the device. The safety box was perceived to be very straightforward. Health workers noted that it was not even necessary to wear gloves to handle the safety box which was perceived as an advantage to them.

Volume

One of the objectives of this study was to assess the impact of needle-remover devices on the volume of needle and syringe waste at health facilities. Using the number of syringes used reported by the health care workers and the number of filled safety boxes and Hub Cutters reported by the supervisors and study facilitators, we calculated the average number of syringes per safety box or per needle container. These numbers are shown for each study site in Table 3 below.

The average number of syringes collected per safety box in sites using Hub Cutters (287) was 35 percent higher than at sites without Hub Cutters (187). More syringes fit in a safety box when the needle is removed; therefore the use of needle removers can reduce the number of safety boxes required.

Table 3. Syringes, Safety Boxes, and Needle Containers Counted During Evaluation

Facility	Syringes Used	Safety Boxes Filled	# of Syringes per Safety Box	Hub Cutters Filled	Average # of Syringes per Hub Cutter
1*	962	9	107	0	
2 *	13,045	49	266	0	
Average for Safety Box Only Facilities			187		
3	4,653	18	259	10	465
4	6,014	21	286	17	354
5	2,527	9	281	3	842
6	1,706	7	244	2	853
7	4,637	4	1,159	3.75**	1,237
8	2,968	12	247	10	297
9	2,569	6	428	4	642
10	8,318	20	416	17	489
11	3,039	15	203	5.75**	529
12	1,296	6	216	2	648
Average for Hub Cutter Facilities***			287***		568***
Total	51,734	176		74.5	

*Facilities only using safety boxes.

**Partially filled Hub Cutter.

***Data from Facility #7 not used in calculation of averages.

As noted in the table above, data from Facility #7 was not used in the calculation of averages for volume. The numbers reported were considerably outside the known range for number of syringes that can fit in a safety box (100-200 according to WHO) and BD's estimates for the number of needles a Hub Cutter can hold (400-600).

Segregation

All participants felt that the Hub Cutter was effective in reducing volume of sharps waste. A major reason for volume reduction is that injection providers were carefully separating clinical waste. Only needles were contained in the Hub Cutters, and only syringes and other sharps (surgical blades, etc.) were placed in the safety boxes. All other medical waste (cotton swabs, gloves, sharps wrappers, etc.) was disposed of in separate containers. Health workers and waste handlers explained that prior to the study, injection providers paid limited attention to segregation of medical waste and often threw everything into one container. It was reported that after the study, most health workers were meticulously placing sharps and other clinical waste in the correct receptacles.

“The injection providers could just mix the waste any how and we could handle it with a lot of risk. But now waste is properly controlled and we are not so much exposed to much risk.”
—Participant from FGD with waste handlers from intervention sites.

Participants explained that it took longer to fill the combination of the Hub Cutter and the safety box than it did to fill the safety box (or other waste container) used on its own. Waste handlers noted that the Hub Cutter decreased the frequency with which clinical waste containers needed to be removed from health clinics and subsequently burned.

Study Closeout

Device Distribution

Following the FGDs in late February, the study monitor distributed the remaining Hub Cutters to the two control facilities. The larger facility received 68 Hub Cutters and the smaller one received 22, expected to be sufficient for three months. In addition, the study monitor reoriented service providers at the control sites in Hub Cutter use, and provided support and guidance to all sites. On April 19–20, 2005, the ten intervention facilities received the remaining Hub Cutters, sufficient for an additional one to two months.

Dissemination of Results

In March 2005 results of the study were reported to a group of study participants from all 12 facilities in a participants feedback meeting.

In order to share preliminary study findings with key stakeholders in Uganda, a dissemination workshop was held on April 14, 2005, in Kampala. PATH staff and the MOH consultant presented findings, and Dr. Victoria Masembe, Country Director of the MMIS project in Uganda and member of UNISTAF, facilitated the meeting. The 32 participants included senior officers from MOH, USAID, DELIVER, nongovernmental organizations, private organizations, and the Uganda government, including several facility managers involved in the study. Questions were raised about device affordability and availability as well as final disposal methods. The manufacturer quoted a price of US\$2.50 to US\$3.00 per unit for public-sector purchase.

Recommendations

The in-country stakeholders made the following recommendations during the dissemination workshop:

- Manufacture the Hub Cutter in several sizes to cater to different sizes of syringes and needles and to adhere to the government policy that waste should not be kept for more than one week before disposal.
- Although incineration is currently recommended by the government of Uganda as the most suitable disposal option for sharps waste, consider other options including standardized sharps pits.
- Leave Hub Cutters and safety boxes at certain outreach sites.
- The Hub Cutter should be able to cut needles without malfunctioning.
- Document the maintenance and cleaning procedures for the Hub Cutter.
- Evaluate the Hub Cutter in rural areas before considering national adoption.
- Manufacture the Hub Cutter locally to reduce costs.
- Bulk purchase by the government could reduce the cost of the Hub Cutter; explore purchase on a credit line, similar to AD syringes.
- Consider disposing syringes into plastic bags, where Hub Cutters are used.
- The Uganda National Injection Safety Task Force should document lessons learned and synergies among various waste management efforts to guide the national waste management policy.

Conclusions

The Hub Cutter was found to fit well into many of the systems in the Kampala clinics. It provides a small, secure, attractive container for storage of a relatively large volume of sharps, which made the clinics cleaner and better organized. The device was well accepted by study participants, who reported that it was extremely dependable and easy to use. Health workers and managers noted that awareness and concern about injection safety and disposal of sharps waste increased, as did staff confidence. Participants felt the device decreased the risk of needlesticks to health workers, clients, waste handlers, and the community at large. The Hub Cutter effectively reduced volumes of clinical waste by approximately 35 percent and allowed consideration of infectious waste bags for disabled syringe barrels.

Challenges associated with Hub Cutter use were final disposal and incompatibility with some sizes of needles. Reported constraints of Hub Cutter disposal highlighted the lack of priority, budgets, and systems for collection, transport, and final disposal of all health care waste. Most facilities lack incinerators and therefore would need to pay for transport and central incineration of Hub Cutters. Without support for proper disposal, Hub Cutters could be left on garbage piles and invite tampering. Infection control protocols made the device unsuitable for use in certain settings where there was more likely to be blood. This could result in confusion as the same health workers provide injections in a variety of settings. The 500+ needle capacity of the Hub Cutter revealed a conflict with infection control protocols which dictated infectious waste be disposed of within a week. In addition, the device was not compatible with very small and large syringe sizes.

Although there were clear advantages to use of the Hub Cutter, we feel that providing it as part of just one vertical program and into an incomplete waste management system is not likely to be of sufficient benefit to outweigh the challenges. The Hub Cutter's unique features may be of greater benefit as part of outreach efforts or in remote, rural settings and could be further evaluated in such environments.

Acknowledgements

The study was conducted in collaboration with the Republic of Uganda, Ministry of Health, Reproductive Health; and Kampala City Council. We gratefully acknowledge the assistance of USAID/Kampala; Dr. Victoria Masembe, Country Director of the MMIS project; Dr. Mubiru, District Director of Health Services, Kampala City Council (KCC); and Sister Helen Oluka of the KCC for her commitment and diligence in monitoring the study and assisting with collecting the data. We are thankful to the clinic managers, health workers, and waste handlers for their participation and commitment to this study.

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Appendix A: Summary of Training

Schedule of the one-day training sessions for intervention and control facility managers, injection providers, and waste handlers.

Facility Managers

Morning:

Project Overview

Injection safety—best practices and needle removal

- Best infection control practices for injections—safety boxes.
- Needle-removal device operation.
- Final disposal of syringes and needles.
- Demonstration.

Standard operating procedures for the evaluation

- Standard operating procedure for the evaluation.
- Completion of the manager's weekly log sheet.
- Standard operating procedures in case of device failure.
- Review definition of malfunction.
- Roles and responsibilities.
- Take home messages.

Injection Providers

Morning:

Project Overview

Injection safety and best practices

- Pretest of knowledge.
- Best practices—infection control for injections.
- Best practices for the collection and disposal of syringes and needles after use (WHO injection safety toolbox tools).
- Practical section.

Use of needle-removal devices (intervention sites)

- Proper operation of the needle-removal devices.
- Definition of device malfunction.
- Separate disposal of the syringes and the needles after use.
- Practical section.

Afternoon:

Standard operating procedures for the evaluation

- Standard operating procedure for the evaluation.
- Completion of the daily log sheet.
- Standard operating procedures in case of multiple device failure.
- Roles and responsibilities.

- Post-test.
- Take home messages.

Waste Handlers

Morning:

Project Overview

Collection and management of sharps waste

- Collection of safety boxes.
- Sealing, securing, and transporting safety boxes.
- Disposal of safety boxes.
- Practical section.

Use of needle-removal devices (intervention sites)

- Collection of Hub Cutters from managers.
- Sealing, securing, and transporting Hub Cutters.
- Disposal of Hub Cutters.
- Practical section.

Standard operating procedures for the trial

- Standard operating procedure for the trial.
- Roles and responsibilities.
- Take home messages.

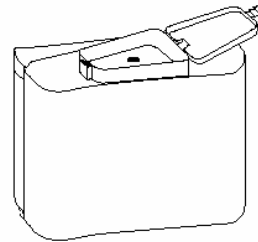
Appendix B: Hub Cutter Instructions for Use

Sharps Disposal Evaluation: Hub Cutter



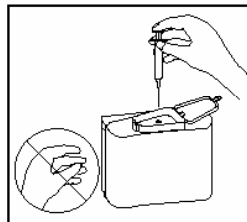
Guidelines for safe use

- A hub cutter device must be placed at each injection station and within arm's reach of the injection provider.
- Do not recap syringes.
- Use hub cutter immediately after injection is given.
- Do not save syringes for later removal of needles.
- Do not hold the hub cutter while inserting needle into the opening.
- Do not overfill the hub cutter.

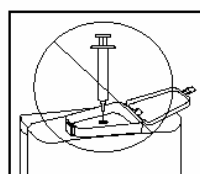
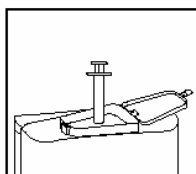


Instructions for use

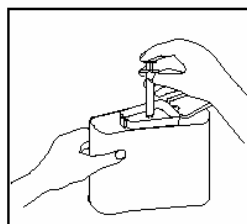
- 1** Place hub cutter on a flat surface. Without holding the hub cutter, insert needle hub vertically and fully into the container opening.



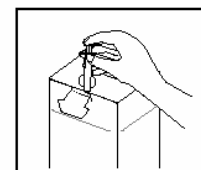
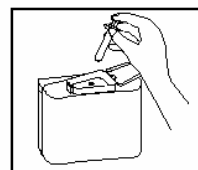
- 2** Make sure the needle is inserted all the way.



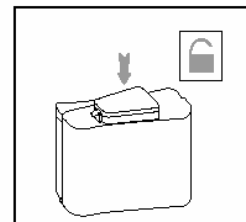
- 3** While holding the syringe in place, squeeze the hub cutter all the way with the other hand to cut the needle hub completely.



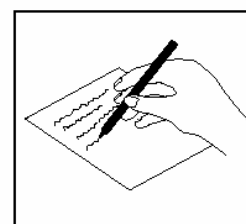
- 4** Release the hub cutter and dispose of the cut syringe in a safety box.



- 5** Close the flip cap, being careful not to engage the lock. Keep flip cap closed between uses.



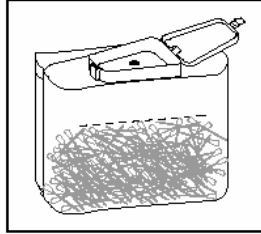
- 6** Each day, complete the daily log for injection providers.



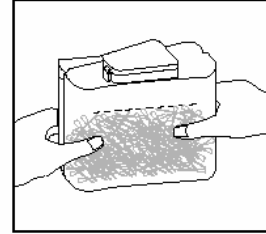
Sharps Disposal Evaluation: Hub Cutter

When device is full

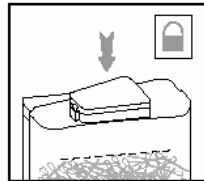
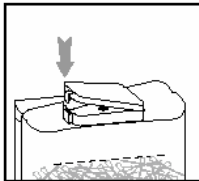
- 1** When the fill line is reached, do not insert any more needles.



- 3** Give device to facility manager for disposal and ask for a new device.

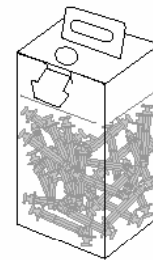


- 2** Lock the flip cap by:
a) inserting the tab into the slot and
b) pressing down firmly until the tab locks into place (audible click will be heard).



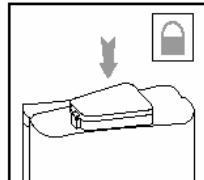
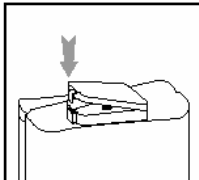
When safety box is full

When the fill line is reached, give the filled safety box to facility manager for disposal and ask for a new safety box.

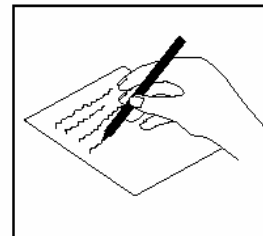


Device malfunction

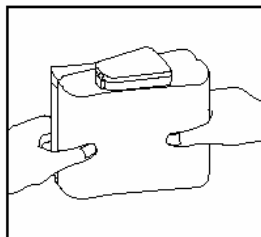
- 1** If the device malfunctions and is no longer able to remove needles, close and lock the device.



- 3** Immediately, complete a device malfunction report.



- 2** Give device to facility manager for disposal and ask for a new hub cutter.

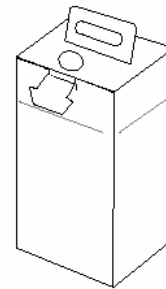


Sharps Disposal Evaluation: Safety Box



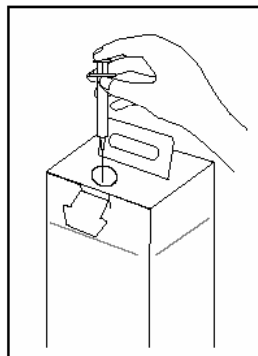
Guidelines for safe use

- A safety box must be placed at each injection station and within arm's reach of the injection provider.
- Do not recap syringes.
- Use safety box immediately after injection is given.
- Do not save syringes for later removal of needles.
- Do not hold the safety box while inserting needle into the opening.
- Do not overfill the safety box.

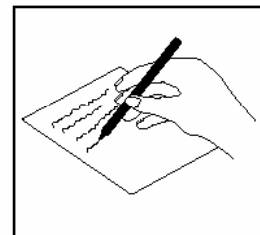


Instructions for use

- 1** After injection, insert syringe into safety box.

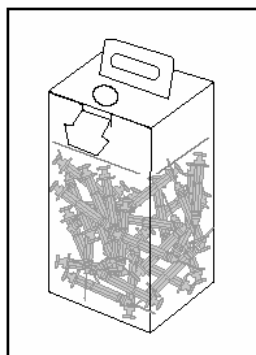


- 2** Each day, complete the daily log for injection providers.



When safety box is full

When the fill line is reached, do not insert any more needles. Give filled safety box to facility manager for disposal and ask for a new safety box.



Appendix D: Daily Log for Injection Providers Using Needle Removers

Injection Provider's Daily log	
1. Date: _ / _ / _ _ _	
2. Facility ID: _____	
3. Total number of injections (including Depo and other types) given today: _____ <i>This number is based on (check one box):</i> <input type="checkbox"/> 1. my daily tally <input type="checkbox"/> 2. injection records	
<div>Daily tally of injections:</div>	
4. Number of Depo injections you gave today: _____	
5. Did any liquid leak from the Hub Cutter? <input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No	
6. Did any needles escape from the Hub Cutter? <input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No	
7. How did the Hub Cutter device work today? (check one) <input type="checkbox"/> 1. Very well <input type="checkbox"/> 2. Satisfactorily <input type="checkbox"/> 3. Poorly <input type="checkbox"/> 4. Did not work	
<i>If device worked poorly or did not work, go to the next question, otherwise stop here.</i>	
8. What was the device number of the device that worked poorly or did not work? (see bottom of device for number) Device No.: _____	
NOTE: If more than one Hub Cutter did not work properly today, please fill in a <u>separate</u> device malfunction form for each additional malfunction.	
9. If the Hub Cutter worked poorly, did it (check one): <input type="checkbox"/> 1. Partially cut the syringe <input type="checkbox"/> 2. Not cut the syringe <input type="checkbox"/> 3. Have a blocked opening <input type="checkbox"/> 4. Took more than 3 attempts to remove needle <input type="checkbox"/> 5. Other (please describe) _____	
10. If the Hub Cutter did not work, were you able to get it to work again? <input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No	
Did the malfunction occur in the (check one box): <input type="checkbox"/> 1. Clinic <input type="checkbox"/> 2. Outreach visit <input type="checkbox"/> 3. Both	

Appendix E: Daily Log for Injection Providers Using Safety Boxes

Injection Provider's Daily log	
1. Date: __/__/__	
<hr/>	
2. Facility ID: _____	
<hr/>	
3. Total number of injections given today: ____	
<i>This number is based on (check one box):</i> <input type="checkbox"/> 1. my daily tally <input type="checkbox"/> 2. injection records	
<div>Daily tally of injections:</div>	
4. Number of Depo injections you gave today: _____	
5. Did any liquid leak from the safety box?	<input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No
6. Did any syringes escape from the safety box?	<input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No
7. How did the safety box work today? (check one)	
<input type="checkbox"/> 1. Very well <input type="checkbox"/> 2. Satisfactorily <input type="checkbox"/> 3. Poorly <input type="checkbox"/> 4. Did not work	
<i>If safety box worked poorly or did not work, describe:</i> _____	

Appendix F: Weekly Log for Managers of Facilities Using Needle Removers

Manager's Weekly log

1. Date: __/__/__

2. Facility ID: _____

3. Total number of safety boxes filled during this week: _____

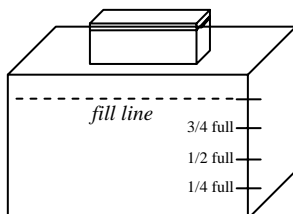
4. How were safety boxes disposed of?

- ☐ 1. Buried
☐ 2. Incinerated
☐ 3. Collected
☐ 4. Burned
☐ 5. Other (describe) _____

5. For each Hub Cutter disposed of this week, fill out one of the boxes below:
(see bottom of device for number)

Device Number: _____

1. Indicate fill level at time of disposal on picture.

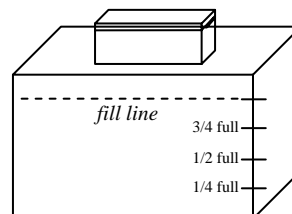


2. How was device disposed of?

- ☐ 1. Buried ☐ 4. Burned
☐ 2. Incinerated ☐ 5. Other: _____
☐ 3. Collected: _____

Device Number: _____

1. Indicate fill level at time of disposal on picture.

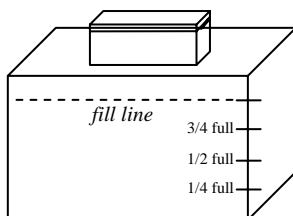


2. How was device disposed of?

- ☐ 1. Buried ☐ 4. Burned
☐ 2. Incinerated ☐ 5. Other: _____
☐ 3. Collected: _____

Device Number: _____

1. Indicate fill level at time of disposal on picture.

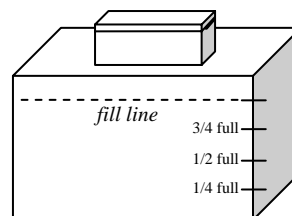


2. How was device disposed of?

- ☐ 1. Buried ☐ 4. Burned
☐ 2. Incinerated ☐ 5. Other: _____
☐ 3. Collected: _____

Device Number: _____

1. Indicate fill level at time of disposal on picture.



2. How was device disposed of?

- ☐ 1. Buried ☐ 4. Burned
☐ 2. Incinerated ☐ 5. Other: _____
☐ 3. Collected: _____

Appendix G: Weekly Log for Managers of Facilities Using Safety Boxes

Manager's Weekly log	
1. Date: _ _ / _ _ / _ _ _ _	
<hr/>	
2. Facility ID: _____	
3. Total number of safety boxes filled during this week: _____	
4. How were safety boxes disposed of?	
<input type="checkbox"/> 1. Buried	
<input type="checkbox"/> 2. Incinerated	
<input type="checkbox"/> 3. Collected	
<input type="checkbox"/> 4. Burned	
<input type="checkbox"/> 5. Other (describe): _____	

Appendix H: Focus Group Discussion Guide for Injection Providers— Intervention Facilities

Consent and Introduction Script

Thank you for taking the time to come to this focus group discussion where we will talk about the needle-remover device you have been using for the past three months. During this discussion, we will talk about your experience using the needle remover and the safety box. I want to hear about your opinions of the device and your impressions of how it fit into your health facility's system. I am interested in the experience that each of you had. There are no right or wrong answers in this sort of a discussion.

This discussion will take about one and a half hours. We will not write down or report on your names. We would like to tape record the session to help us capture the whole discussion. The study investigator will try to keep any information you share today confidential. We ask each of you to respect each other's privacy and request that whatever other people talk about during this session should remain in this room and should not be discussed after the session is completed. However, because we have no control over what people do when they leave the focus group discussion, we cannot promise confidentiality.

Your choice to take part in this discussion is completely voluntary. You may leave if you want to and it will not affect your job in any way. If any one does not feel comfortable having the session taped, we will not tape it. If you have any questions please feel free to ask them now or during the brief break we will have before we begin the focus group.

Needle disposal with new device

1. Has each one of you used this Hub Cutter needle remover device? In what situations did you use it? (Probe: Clinic, outreach, FP, MCH, OPD. Did you take it from one ward to another—from FP to outreach? What sizes and types of needles and syringes did you use with the Hub Cutter?)
2. Where was the Hub Cutter located in the clinic? In outreach settings? When did you use the Hub Cutter—as soon as the injection was given or later?
3. Tell me about its reliability. (Probe: How well did the device work? Was it reliable? If not, what happened? Did it work with all types of needles? If not, what did you do with these?)
4. Was a Hub Cutter always available when you gave injections? If not, why not? (Probe: What did you do if it was not working or not available? Where did you store it when it was full? How many places are Hub Cutters needed?)
5. What about maintaining the needle remover? (Probe: Did it always work? If not, why not? Was anything done to keep it in working order? Was it cleaned? How? How often?)
6. Did you have sufficient training to be able to use the Hub Cutter? (Probe: On-the-job training? IEC materials and small instructions on Hub Cutter device?)
7. What did you like about the device? (Probe: Ease of use, make job easier or harder, access, containment of sharps, prevent reuse, personal safety, community safety, cleanliness of facility, reduced volume of waste.)

8. What things did you dislike about the device? (Probe: Malfunctioned, hard to use, not available when needed, did not work with all syringes, time requirements, still required safety box for syringe barrel, needles or liquid escaped, felt unsafe.)
9. How is this way of handling sharps different from what you used prior to this study? (Probe: Is this device better or worse? Advantages and disadvantages of Hub Cutter and previous method. How did you feel about destroying the needle and syringe?)
10. Has the Hub Cutter changed the way you work? In what ways?
11. What affect did the monitoring have on your work?
12. How could the design of the Hub Cutter be improved?
13. How did the needle-remover device change your handling of needles and syringes?(What did you do with the used syringes?)
14. How did the patients react to your use of the Hub Cutter device?
15. In what settings is the Hub Cutter most useful? (Probe: Outreach, busy clinic, or hospital?)

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